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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,881	01/11/1999	THAI D. NGUYEN	07425.0057	7578

7590

03/04/2002

David R. Marsh
ARNOLD & PORTER
555 12TH Street, N.W.
Washington, DC 20004-1206

EXAMINER

SCHMIDT, MARY M

ART UNIT PAPER NUMBER

1635

DATE MAILED: 03/04/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

SEE ATTACHED



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EXAMINER

NGUYEN, LIEN-CHI A

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*Restarted -
action was
returned
to
office 2/21/02*

Office Action Summary

Application No.

09/227,881

Applicant(s)

NGUYEN ET AL.

Examiner

Lauren Nguyen

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213

Disposition of Claims

- 4) ☒ Claim(s) 79-81 and 91-126 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 79,81,91,94,97,103,106,109,115,118 and 121 is/are rejected.
- 7) ☒ Claim(s) 80,92,93,95,96,98-102,104,105,107,108,110-114,116,117,119,120 and 122-126 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election of Restriction Requirement

1. Applicants election of Group III, claims 79-81, 91, 94, 96, 97, 100, 102, 103, 106, 108, 109, 112, 114, 115, 118, 120, 121, 124, and 126 encompassing SEQ ID No. 3, with traverse in Paper No. 23 is acknowledged.

The traversal is on the ground(s) that the Examiner has not shown that a search and examination of the entire application would cause a serious burden. This is not found persuasive because as stated in the Restriction Requirement, filed as Paper No. 19, the invention of groups I-IV are unrelated, each from the other, since it can be shown that the inventions of groups I-IV are not disclosed as capable of use together and also, the inventions have different modes of operation, different function, or different effects (MPEP 806.04 and 808.01). In this instant case, the different inventions are drawn to different nucleotide sequences such that each different SEQ ID would require a separate nucleotide search. Therefore, searching all of SEQ ID Nos. 1-3, 34, 37, 38 and their respective fragments would constitute a burdensome search on the nucleotide sequence searching resources of the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

~~The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.~~

DETAILED ACTION

Election of Restriction Requirement

1. Applicants election of Group III, claims 79-81, 91, 94, 96, 97, 100, 102, 103, 106, 108, 109, 112, 114, 115, 118, 120, 121, 124, and 126 encompassing SEQ ID No. 3, with traverse in Paper No. 23 is acknowledged.

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The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1635

2. Claims 79, 81, 91, 97, 109, 115, and 121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 79, 81, 91, 97, 109, 115, and 121 recite "...a substantially purified nucleic acid..." Without providing a definition of the term "substantial" in the specification or the claims, one of ordinary skill would not be able to assess the metes and bounds of the limitation encompassed within the term "substantial" in regards to the purity of the isolated nucleic acid, for example. Therefore, recitation of said term renders the claim indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 91, 94, 103, 106, 115, and 118 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 45 of U.S. Patent No. 6,171,788. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 91 and 94 are anticipated by claim 45 of U.S. Patent No.

6,171,788 and claims 103, 106, 115 and 118 are obvious modifications from claim 45 of U.S.

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Patent No. 6,171,788. Claims 91 and 94 are drawn to a substantially purified nucleic acid comprising a nucleotide sequence selected from the group consisting of SEQ ID No. 3 wherein the nucleotide sequence comprises a functional regulatory region. Claims 103 and 106 are drawn to a cell comprising an introduced nucleic acid selected from the group consisting of SEQ ID No. 3 wherein the nucleotide sequence comprises a functional regulatory region. Claims 115 and 118 are drawn to a vector comprising a substantially purified nucleic acid wherein the nucleic acid comprises a nucleotide sequence selected from the group consisting of SEQ ID No. 3 wherein the nucleotide sequence comprises a functional regulatory region.

Claim 45 of U.S. Patent No. 6,171,788 recites a nucleic acid molecule that comprises the sequence of SEQ ID No. 3.

The nucleotide sequence of SEQ ID No.3 in U.S. Patent No. 6,171,788 is 100% identical to the nucleotide sequence of SEQ ID No. 3 in the instant application. It would have been obvious to one of ordinary skill to make and use a vector and transformed cell comprising SEQ ID No. 3 in light of the identically disclosed sequence in U.S. Patent No. 6,171,788.

Claim Objection to Allowable Subject Matter

4. Claims 80, 92, 93, 95, 96, 98, 99, 100, 101, 102, 104, 105, 107, 108, 110-114, 116, 117, 119, 120, and 122-126 would be allowable if rewritten in independent form and to include all of the limitations of the base claim and any intervening claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Nguyen, Ph.D. whose telephone number is 703-308-0256. The examiner can normally be reached on Monday-Friday 9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-7939 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Lauren Nguyen, Ph.D.
January 13, 2002

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SEAN MCGARRY
PRIMARY EXAMINER

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